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APR - 5 2010

3. 510(K) SUMMARY

1. Applicant/Sponsor: Corin USA
10500 University Center Drive
Suite 190
Tampa, Florida 33612
Establishment Registration No.:

2. Contact Person: Ashlea Bowen, AA, RAC
Regulatory Affairs Associate
Corin USA
813-977-4469
ashlea.bowen@coringroup.com

3. Proprietary Name: MiniHip Stem

4. Common Name: Femoral Hip Stem

5. Classification Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21CFR 888.3353)

6. Legally Marketed Devices to which Substantial Equivalence is claimed:
   a. Howmedica Osteonics Secur-Fit Max Hip and Secure-Fit Plus Max Hip Stems (K051738)
   b. Aesculap Implant Systems Metha Short Stem Hip System (K080584)
   c. Zimmer MAYO Conservative Hip Prosthesis (K030733)
   d. Smith & Nephew MIS Hip Stem (K072417)

7. Device Description:

   The MiniHip Stem is a titanium femoral hip stem featuring a 12/14 tapered male trunnion for assembly with modular femoral head components. The MiniHip Stem uses a short stem philosophy to provide a bone-conserving option to the use of a standard total hip prosthesis. The stem is manufactured from Titanium ($TiAl_6V_4$) alloy and is proximally coated with plasma sprayed hydroxyapatite over plasma sprayed pure titanium in order to enhance primary fixation. The stem is designed to be used in conjunction with Corin Eurocone CoCr modular femoral heads (K003666) and Corin Zyranox Zirconia Ceramic modular femoral heads (K992235), both of which mate with Corin Cenator Acetabular Cups (K925866). The stem is available in six sizes, each with the provision of a 130° CCD (Caput-Collum-Diaphysis) neck angle with a polished distal section for guidance and to minimize distal fixation and reduce proximal stress-shielding.

8. Intended Use / Indications:

The indications for the MiniHip Stem as a total hip arthroplasty include:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity
- DDH/CDH
- Revision procedures where other treatments or devices have failed
- Treatment of non-union, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

The MiniHip Stem is indicated for cementless use only.

9. Summary of Technologies/Substantial Equivalence:

The MiniHip Stem has the same intended use and indications as the four predicate devices. In addition, the MiniHip Stem is similar in design and available in sizes within the range of the MIS Hip Stem (K072417). The stem is manufactured from the same material and demonstrates similar characteristics as all four predicate devices. The proximal coating of plasma-sprayed HA over plasma-sprayed titanium is the equivalent to that applied to the Secur-Fit Max Hip and Secur-Fit Plus Max Hip Stems (K051738). Based on these similarities, Corin believes that the MiniHip Hip Stem is substantially equivalent to the predicate devices.

10. Non-Clinical Testing:

Non-clinical testing and analysis included mechanical fatigue testing, range of motion testing and coating characterization. The results of this testing show that the MiniHip Stem is expected to be safe and effective for the proposed indications and is substantially equivalent to the predicate device.

11. Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the MiniHip Stem and the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Corin U.S.A
% Ms. Ashlea Bowen, AA, RAC
Regulatory Affairs Associate
10500 University Center Drive, Suite 190
Tampa, Florida 33612

APR - 5 2010

Re: K083312
Trade/Device Name: MiniHip Stem
Regulation Number: 21 CFR 8888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prothesis
Regulatory Class: II
Product Code: LZO
Dated: February 26, 2010
Received: March 1, 2010

Dear Ms. Bowen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. INDICATIONS FOR USE

510(k) Number (if known): K083312

Device Name: MiniHip Stem

Indications for Use:

The indications for the MiniHip Stem as a total hip arthroplasty include:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity
- DDH/CDH
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The MiniHip Stem is indicated for cementless use only.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K083312